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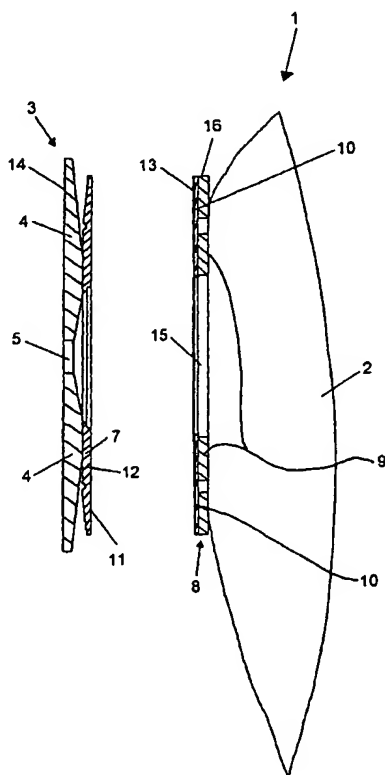
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- (71) Applicant (*for all designated States except US*): COLOPLAST A/S [DK/DK]; Høltedam 1, DK-3050 Humlebaek (DK).
- (72) Inventor; and
- (75) Inventor/Applicant (*for US only*): LEISNER, Henrik [DK/DK]; Maglemøsevej 49, DK-2900 Hellerup (DK).

[Continued on next page]

(54) Title: AN OSTOMY DEVICE COMPRISING A COLLECTING BAG AND A BASE PLATE AND AN OSTOMY COLLECTING BAG



(57) Abstract: An ostomy device (1) comprising a collecting bag (2) and a base plate (3) with an adhesive plate (4) for being fastened on the user, said base plate (3) further comprising a first flange (7) for repeated and removable adhesive connection to a coupling element (8) on the collecting bag, said first flange (7) being manufactured from a material with a first tensile strength, said coupling element comprising a second flange (9) manufactured from a material with a second tensile strength, said adhesive connection being provided by at least one layer of an adhesive (13). Furthermore, the device comprises a further flexible layer (10) placed between the adhesive and the flange with the tensile strength being the lowest, and said flexible layer having a yield strength exceeding the adhesive strength of the adhesive (13). Hereby an adhesive coupling connection is obtained between bag part and body portion in such a manner that deformations and tearing out of the flange material are prevented and whereby good coupling connection is obtained without a risk of residue of adhesive agent and foam being left behind on the surface the was supposed to be clean and ready to receive an fresh, unused bag flange.



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# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference <b>P200201474 WO</b>	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. <b>PCT/DK 03/00736</b>	International filing date ( <i>day/month/year</i> ) <b>30.10.2003</b>	Priority date ( <i>day/month/year</i> ) <b>31.10.2002</b>
International Patent Classification (IPC) or both national classification and IPC <b>A61F5/448</b>		
Applicant <b>COLOPLAST AS ET AL.</b>		
<p>1. This International preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 4 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheets.</p>		
<p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> <li>I <input checked="" type="checkbox"/> Basis of the opinion</li> <li>II <input type="checkbox"/> Priority</li> <li>III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</li> <li>IV <input type="checkbox"/> Lack of unity of invention</li> <li>V <input checked="" type="checkbox"/> Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</li> <li>VI <input type="checkbox"/> Certain documents cited</li> <li>VII <input type="checkbox"/> Certain defects in the international application</li> <li>VIII <input type="checkbox"/> Certain observations on the international application</li> </ul>		
Date of submission of the demand  <b>13.03.2004</b>	Date of completion of this report  <b>01.09.2004</b>	
Name and mailing address of the international preliminary examining authority:   European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer  <b>Hedels, B</b>  Telephone No. +49 89 2399-2329  	

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/DK 03/00736

**I. Basis of the report**

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

**Description, Pages**

1-12 as originally filed

**Claims, Numbers**

1-10 as originally filed

**Drawings, Sheets**

1/1 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. **PCT/DK 03/00736**

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Yes: Claims	1-10
	No: Claims	
Inventive step (IS)	Yes: Claims	1-10
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-10
	No: Claims	

**2. Citations and explanations**

**see separate sheet**

**Concerning section V.:**

1. An ostomy device and an ostomy collecting bag as defined in the preamble of the independent claims 1 and 9, respectively, is disclosed in EP-A-0 793 951 (D1).

The problem of the invention was to provide an ostomy device and an ostomy bag providing an adhesive coupling between the body portion and the bag such that deformations and tearing out of flange material of the body part and the bag are prevented.

This problem is solved in that a further flexible layer is placed between the adhesive and the flange of the bag with the tensile strength of the flexible layer being lower than the tensile strength of the flange of the base plate and the flange of the bag, said flexible bag having a yield strength exceeding the adhesive strength of the adhesive.

These features are novel and they cannot be derived in an obvious manner from the cited documents.

Moreover, such an ostomy device and collecting bag are industrially applicable such that all the requirements of Art. 33(2)-(4) PCT are met.

2. The dependent claims 2-8 define particular embodiments of the invention according to claim 1 and claim 10 defines the utilisation of the bag according to claim 9. Thus, these claims also meet the requirements of Art. 33(2)-(4) PCT.

3. D1 should in addition have been indicated in the description (Rule 5.1 (a) (ii)).